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Michael O. Leavitt, Administrator
U.S. Environmental Protection Agency
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PETA
PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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Comments on the HPV test plan for N,N-dimethylacetoacetamide (DMAA)

Dear Administrator Leavitt:

The following comments on the Color Pigments Manufacturers Association (CPMA) test plan for DMAA (CAS no. 2044-64-6) are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These animal, health, and environmental protection organizations have a combined membership of more than ten million Americans.

The CPMA is proposing to conduct a combined repeat-dose, reproductive and developmental toxicity test (OECD no. 422) on DMAA. This test will kill at least 675 animals.

First, the test plan suggests that DMAA is a closed-system intermediate (pp. 3, 5). The CPMA should clarify this point. If DMAA is indeed a closed-system intermediate then, according to the EPA, repeated-dose and reproductive toxicity data are not required (Wayland, 1999).

Second, the common sense approach to reducing the number of animal tests, as encouraged by the EPA in the above-referenced letter to chemical sponsors, would be for the CPMA to provide some information about the potential for human exposure, such as the number of sites where DMAA is handled, and the numbers of employees at those sites. If, for example, the potential for exposure is very low, and all personnel with the potential for exposure are male, then, taking into account the low toxicity of DMAA (LD_{50} > 3.2 g/kg), no developmental toxicity data should be required. A survey carried out in the 1980's reported that 1,363 workers were exposed annually to DMAA, yet none of these were female (NIOSH). These data are presumably out of date if DMAA is now a closed-system intermediate, but they are suggestive.

To summarize, the CPMA should submit a revised test plan, with far more information about the use of, and actual and/or potential exposure to, DMAA.

Finally, the CPMA states that it intends to carry out an *in vitro* chromosomal aberration study (OECD no. 473) on DMAA. We urge the CPMA to use either human lymphocytes or mammalian cells obtained from established cultures, so as to avoid killing additional animals in order to supply the cells.

I can be reached at 757-622-7382, ext. 8001, or via e-mail at JessicaS@peta.org.

Sincerely,

Jessica Sandler
Federal Agency Liaison

References

NIOSH, *National Occupational Exposure Survey (1980-1982)*, http://www.cdc.gov/noes/noes1/x9581sic.html.

Wayland, S.H., "Letters to manufacturers/importers," October 14, 1999, http://www.epa.gov/chemrtk/ceoltr2.htm.